Attorney Docket No.: P-71486-US2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	KILCOYNE, John T. et al.	Examiner:	NGUTEN, HUONG Q
Serial No.:	10/687,336	Group Art Unit:	3736
Filed:	October 16, 2003	Confirmation No.:	7853
Title:	IMPLANTABLE MONITORING PROBE		

APPEAL BRIEF

Mail Stop **Appeal Brief – Patents**
Board of Patent Appeals and Interferences
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I. Real Party in Interest

The real parties in interest in this Appeal are Given Imaging, Ltd., ("Given") an Israeli corporation, the assignee of U.S. Patent Application No. 10/687,336, and its U.S. subsidiary, Given Imaging Inc., of Norcross, Georgia.

II. Related Appeals and Interferences

There are no prior or pending litigations, appeals or interferences known to Applicants that may be related to, may directly affect, or may be directly affected by or have a bearing on the Board's decision in this Appeal.

III. Status of the Claims

Claims 1-49 have been cancelled. Claims 50-60 are pending, have been finally rejected and are appealed.

IV. Status of Amendments

No amendments have been filed subsequent to the Final Office Action of August 8, 2011 (the "Final Office Action").

V. Summary of Claimed Subject Matter

The following is an explanation of the subject matter defined in each of the independent claims involved in this appeal, referring to the relevant page and line numbers in the specification and to drawing elements.

Independent claim 50 relates to a system for measuring physiological parameters in the body of a patient indicative of gastroesophageal reflux, the system comprising: a monitoring device (Figure 1 ref. no. 18), the monitoring device including a housing (Figure 4 ref. no. 120) adapted to be implanted in the body of a patient by attachment to tissue inside the body (Fig. 1, ref. nos. 4-7 and 12-22E, page 8 lines 13-28, page 12, line 22 to page 25, line 29), and a plurality of sensors (e.g., p. 10, lines 10-12, sensors within transducer 110) included in the housing, where each of the plurality of sensors is capable of independently measuring a different respective physiological parameter indicative of gastroesophageal reflux (Fig. 2, page 10, line 7 to page 10, line 28, page 25, lines 30 to page 26, line 3) and where the monitoring device periodically transmits a signal indicative of the value of the respective physiological parameter measured by each of the plurality of sensors (Figs. 2, ref. nos. 23 and 24, page 10, line 29 to page 11, line 27, page 15, lines 10-19, and page 27, line 14 to page 29, line 24); and

a receiver (Figure 1 ref. no. 32) that receives the signals from the monitoring device (Figure 1 ref. no. 18), the signals representing measurements made by the respective sensors, monitors the physiological parameters indicative of gastroesophageal reflux based on the received signals, and determines the presence of gastroesophageal reflux based on each of the signals received from the of sensors (Fig. 1, page 8, line 24 to page 9, line 3 page 10, lines 15-28, and page 25, lines 30 to page 26, line 3).

VI. Grounds of Rejection to be Reviewed on Appeal

The following grounds of rejection are to be reviewed in this Appeal:

A. The Examiner's contention that claims 50, 51 and 58-60 are unpatentable under 35 USC §103(a) over Anggiansah et al., "Primary Peristalsis is the Major Acid Clearance Mechanism in Reflux Patients" ("Anggiansah"), in view of Johnsson et al., "Determinants of Gastroesophageal Reflux and their Interrelationships" ("Johnsson").

B. The Examiner's contention that claims 52-55 are unpatentable under 35 U.S.C. § 103(a) over Anggiansah in view of Johnsson and further in view of U.S. Patent No. 5,984,875 to Brune ("Brune").

C. The Examiner's contention that claims 56-57 are unpatentable under 35 U.S.C. § 103(a) over Anggiansah in view of Johnsson and Brune, and further in view of U.S. Patent No. 6,416,471 to Kumar et al. ("Kumar").

VII. Argument

1. Claims 50, 51 and 58-60 are Patentable Under 35 USC §103(a) Over Anggiansah in View of Johnsson

In the Final Office Action, the Examiner rejected claims 50, 51 and 58-60 under 35 U.S.C. § 103(a), as being unpatentable over Anggiansah in view of Johnsson. Appellants respectfully traverse this rejection in view of the remarks that follow.

Applicants' independent claim 50 requires, *inter alia* "a receiver that ... determines at least the presence of gastroesophageal reflux based on each of said plurality of signals received from said plurality of sensors" where "each of the plurality of sensors is capable of independently measuring a different respective physiological parameter." Thus claim 50 describes a system that can determine gastroesophageal reflux based on multiple different parameters, e.g., pH and pressure, rather than only one parameter. Each of the prior art references to which the Examiner cites (specifically Anggiansah and Johnsson) describes using the same single parameter – pH – to determine reflux. The Examiner asserts that these references in combination use both pH (Anggiansah) and pressure (the Examiner asserts that

based on Johnsson, one would use pressure) to determine reflux. However, as described below, Johnsson determines reflux based on pH, not pressure.

Anggiansah describes a study regarding acid clearance mechanisms in patients with gastro-oesophageal reflux disease. Gastro-oesophageal reflux disease is a medical condition in which a portion of the acidic contents of the stomach returns to the esophagus. This medical condition is characterized by an abnormal pH level in the esophagus. Anggiansah describes that acid clearance from the oesophagus after gastro-oesophageal reflux depends on oesophageal peristalsis (page 1536, bottom of left column and top of right column). In order to investigate the oesophageal motor pattern in gastro-oesophageal reflux patients, the pressure level is monitored in several locations in the esophagus (page 1537, top of left column and top of right column). Since the pH level in the esophagus is indicative of gastro-oesophageal reflux, it is monitored in Anggiansah in order to ensure that the study is performed during a condition of abnormal gastro-oesophageal reflux (page 1536, bottom of right column and page 1537, bottom of left column). Therefore, according to Anggiansah the pH level is measured for detection of gastro-oesophageal reflux, and the pressure is measured to detect the intensity and pattern of the oesophageal peristalsis.

Additionally, Anggiansah discloses that the pressure sensors are on a separate catheter than the pH sensors (page 1357), and that the catheters are inserted through the nose into the stomach and secured to the patient with micropore tape (page 1537, middle of left column), i.e. the catheters are secured to the patient's skin, externally to the body, and apart from that external attachment the catheters can sway freely inside the esophagus.

Similarly to Anggiansah, Johnsson discloses that the pH level is monitored in order to detect gastro-oesophageal reflux (page 241, right column). Additionally, Johnsson discloses that the pressure in the distal oesophageal high pressure zone correlated most strongly to the *amount* of gastro-oesophageal reflux (abstract and Table 1 in page 242), where the amount of reflux is the percentage of time during the monitoring when pH was smaller than 4 (page 241, right column). The study emphasized the role of the pressure as the primary antireflux barrier (abstract). Therefore, according to Johnsson, by measuring the pressure level in the distal oesophageal high pressure zone one can estimate the amount of gastro-oesophageal reflux in the monitored esophagus. However, Johnsson does not detect and does not enable detection of gastro-oesophageal reflux *itself* by measuring pressure level.

Applicants' currently pending claim 50 includes, *inter alia*: "a monitoring device, said monitoring device comprising a housing adapted to be implanted in the body of a patient *by attachment to tissue inside the body*." (emphasis added).

On page 3 of the Final Office Action, the Examiner asserts that Anggiansah discloses a system for measuring physiological parameters in the body of a patient indicative of gastroesophageal reflux, the system comprising a monitoring device, said monitoring device comprising a housing adapted to be implanted in the body of a patient by attachment to tissue inside the body (the Examiner cites to using micropore tape; Anggiansah, p. 1537 left col.). The Examiner asserts that www.dictionary.com defines implant as "inserted into the body." The Examiner further asserts that "[t]he tape used to secure the catheter even if placed *outside* the body nevertheless causes 'attachment to tissue *inside* the body'," and notes that the claims do not recite the location and nature of said attachment (See Final Office Action, pages 8 and 9; emphasis added). Appellants respectfully disagree with these assertions.

The Examiner cited definition of "implant" as being "to insert into the body" is incomplete. The "implant" entry at dictionary.com defines the verb implant as (emphasis added):

1. to put or fix **firmly**: to implant sound principles in a child's mind.
2. to **plant** securely.
3. Medicine/Medical. to insert or graft (a tissue, organ, or inert substance) into the body.

(http://dictionary.reference.com/browse/implant)

Therefore, an object should be fixed firmly or securely in order to be said to be implanted. An object that is merely inserted into the body, like an aspirin tablet being swallowed, is not implanted inside the body. Similarly, an object that is inserted into the body and taped externally to the skin is not implanted inside the body, but rather has a portion attached outside the body and a different portion inserted inside the body, and cannot be said to be attached to a tissue inside the body. It cannot be said that Anggiansah's catheters are fixed firmly or implanted securely inside the body, for example in the patient's esophagus. Essentially, Anggiansah's catheters dangle freely in the esophagus, being secured only externally to the body, for example to the patient's cheek. There is a substantive difference between the prior art, e.g., Anggiansah, and a device according the Applicants' claimed

invention, which affects the device's functionality and the patient experience. For example, securing of the device inside the body as in the presently claimed invention makes unnecessary the uncomfortable permanent presence of the catheter through the nose. In a typical device according to the presently claimed invention, once the device is implanted inside the body, the patient may not notice the device. Additionally, implanting in the body, as opposed to securing the device outside the body, may facilitate less limited implantation of multiple devices with, for example, various sensors in different locations in the esophagus. Taping the device outside the body, as in the prior art, eliminates the need for securing or attachment inside the body (e.g., by affixing to the esophageus, see, e.g., p. 20 of Applicants' specification).

Contrary to the Examiner's allegation on page 9 of the Office Action that "the claims do not recite the location and nature of said attachment", Applicants' claim 50 recites "... implanted in the body of a patient by attachment to tissue inside the body." The attachment location provided in claim 50 is "*inside* the body" and the nature is "by *attachment to tissue inside* the body". (emphasis added) This recited location and nature of the attachment are not disclosed in Anggiansah. Attachment of a device to a tissue outside the body, as disclosed in Anggiansah, is not equivalent to attachment of a device to a tissue inside the body, as required in claim 50.

Anggiansah does not explicitly disclose attachment of a device to internal body tissue. Not only does Anggiansah not suggest this internal attachment, but the *external* attachment of Anggiansah (using tape) makes the internal attachment of Applicants' claim 50 unnecessary. Thus Anggiansah teaches away from Applicants' claim 50.

Therefore, Anggiansah does not teach or suggest, and teaches away from, at least "said monitoring device comprising a housing adapted to be implanted in the body of a patient by attachment to tissue inside the body", as recited in claim 50.

Additionally, on pages 3-4 of the Final Office Action, the Examiner asserts that Anggiansah discloses "a plurality of sensors included in said housing, wherein each of the plurality of sensors is capable of independently measuring a different respective physiological parameter indicative of gastroesophageal reflux", as recited in Applicants' claim 50. Appellants respectfully disagree. Anggiansah's system includes a commercial pH

sensing catheter (Synectics Medical, Sweden) and a separate commercial pressure sensing catheter (Gaeltec, Isle of Skye, UK). The two catheters are not placed *in* a housing, as is claimed, but rather they are *bonded* together for the purpose of the study (see Anggiansah, p. 1537, right col.). It cannot be said that the Anggiansah sensors are all included in the same housing, as they are located a few centimeters apart from each other on the separate catheters. Two catheters *bonded* together is not equivalent to the sensors being *housed* together. Therefore, Anggiansah does not teach or suggest at least "a plurality of sensors included in said housing, wherein each of the plurality of sensors is capable of independently measuring a different respective physiological parameter indicative of gastroesophageal reflux", as recited in claim 50.

Applicants note that claim 50 requires the sensors be "in" a housing, which contrasts physically and in terms of function from sensors being "on" a housing as the Examiner asserts on page 9 of the Final Office Action. Two separate catheters bonded to one another does not equate to two sensors "in" a housing.

Further, according to the Examiner, Anggiansah's system *necessarily* contains a housing structure on which said sensors are placed (Final Office Action, p. 9). On the contrary, two separately obtained, commercially available catheters, each of which can be used separately (the pH sensing catheter of Synectics Medical and the pressure sensing catheter of Gaeltec), almost necessarily are *not* placed in the same housing. Again, Anggiansah teaches away from one of Applicants' claim elements.

The Examiner acknowledges on page 4 of the Final Office Action that Anggiansah does not expressly disclose that the determination of gastro-oesophageal reflux is based upon both the pH and pressure signals. The Examiner then cites to Johnsson, which, according to the Examiner, teaches that pressure data is highly valuable in gastro-oesophageal reflux determination and is the single variable that correlates most strongly to the amount of reflux determined using at least pH monitoring. According to the Examiner, since Johnsson teaches that pressure data is so valuable in the determination of gastroesophageal reflux, it would have been obvious to one of ordinary skill in the art to have the determination of gastro-oesophageal reflux performed by Anggiansah be made with both pH and pressure signals.

Appellants respectfully disagree with the Examiner's assertions. As argued above, Johnsson teaches only that pressure is an important factor in determining the *amount* of reflux, not the *presence* of reflux. Appellants note further that, in Johnsson, the presence of reflux appears to be determined using a similar sensor as that in Anggiansah; that is, by pH. For example, Figure 1 in Johnsson is the "[r]elation between pressure in the distal oesophageal high pressure zone and percentage of time with pH<4 by pH monitoring." In the "Patients and methods" section of Johnsson, on page 241, right column, reflux is determined by pH: "[t]he amount of gastro-oesophageal reflux was expressed as the percentage of time during the monitoring when pH was <4 in the oesophagus." This is similar to Anggiansah where a "reflux episode was defined as starting when pH fell to less than 4 and ending when the pH rose to 5" (see Anggiansah, Abstract). Thus, as in Anggiansah, Johnsson uses only pH to determine the *presence* of reflux, while pressure is used to correlate the *amount* of reflux.

Appellants note that Johnsson is a study as to what extent various parameters correlate to the amount of reflux. The Examiner relies in Johnsson on a correlation between the pressure in the distal oesophageal high pressure zone and the *amount* of reflux. Appellants note that Johnsson does not teach or suggest anything regarding a correlation between pressure and the *presence* of reflux. As such, Appellants point out that Johnsson does not add any relevant teaching to Anggiansah with respect to determining the presence of gastro-oesophaageal reflux. Therefore, the combination of Johnsson an Anggiansah does not disclose or make obvious, *inter alia*, "a receiver that ... determines at least the presence of gastroesophageal reflux based on each of said plurality of signals received from said plurality of sensors", as recited in claim 50.

Additionally, in Johnsson, pressure is measured in the distal esophageal high pressure zone, whereas in Anggiansah it is measured in various regions of the esophagus. Appellants respectfully assert that the correlation between distal esophageal pressure and amount of reflux in Johnsson is sufficiently different from Anggiansah's measurement of pressure throughout the esophagus, such that a person of skill in the art would not combine the two. While the pressure measurements in Anggiansah, in various locations in the esophagus, have an intended use of studying the acid clearance mechanism in gastro-oesophageal reflux patients, the pressure measurements in Johnsson have an intended use of studying the role of the pressure level in the distal oesophageal high pressure zone as a primary antireflux barrier

(see abstract). Therefore, a person skilled in the art at the time the invention was made would not deduce from Johnsson's results regarding the correlation between pressure and amount of reflux anything regarding the possible conclusions of the pressure measurements disclosed in Anggiansah.

In view of the foregoing, Appellants respectfully assert that independent claim 50 is allowable over Anggiansah in view of Johnsson. Each of claims 51 and 58-60 depends from independent claim 50 and therefore includes all the limitations of that claim. At least for this reason, claims 51 and 58-60 are likewise allowable.

Accordingly, Appellants respectfully submit that claims 50, 51 and 58-60 are patentable under 35 U.S.C. § 103(a) over Anggiansah in view of Johnsson.

2. Claims 52-55 are Patentable Under 35 U.S.C. § 103(a) Over Anggiansah in View of Johnsson and Further in View of Brune

In the Final Office Action, the Examiner rejected claims 52-55 under 35 U.S.C. § 103(a), as being unpatentable over Anggiansah in view of Johnsson and further in view of Brune. Appellants respectfully traverse this rejection.

Each of claims 52-55 depends from claim 50 and therefore includes all the limitations of that claim. Brune discloses an ingestible animal temperature sensor that includes a controller and a transmitter (column 6, lines 22-42) and does not cure the deficiencies of Anggiansah in view of Johnsson discussed in detail above with reference to claim 50. At least for this reason, claims 52-55 are likewise allowable.

Accordingly, Appellants respectfully submit that claims 52-55 are patentable under 35 U.S.C. § 103(a) over Anggiansah in view of Johnsson and further in view of Brune.

3. Claims 56 and 57 are Patentable Under 35 U.S.C. § 103(a) Over Anggiansah in View of Johnsson and Brune, and Further in View of Kumar

In the Final Office Action, the Examiner rejected claims 56 and 57 under 35 U.S.C. § 103(a), as being unpatentable over Anggiansah in view of Johnsson and Brune, and further in view of Kumar. Appellants respectfully traverse this rejection.

Each of claims 56 and 57 depends from claim 50 and therefore includes all the limitations of that claim. Kumar discloses a portable remote patient telemonitoring system

that has a signal transfer unit carried by the patient (column 11, lines 35-41). Kumar does not cure the deficiencies of Anggiansah in view of Johnsson and Brune discussed in detail above with reference to claim 50. At least for this reason, claims 56 and 57 are likewise allowable.

Accordingly, Appellants respectfully submit that claims 56 and 57 are patentable under 35 U.S.C. § 103(a) over Anggiansah in view of Johnsson and Brune and further in view of Kumar.

Conclusion

In view of the foregoing arguments, and for at least the reasons discussed above, Appellants respectfully submit that the final rejection should be reversed and claims 50-60 should be allowed.

This is an Appeal Brief for which a fee of $620.00 is due under 37 CFR 41.20(b)(2). Please charge Deposit Account No. 50-3355 for this fee, as well as any additional fees due. A duplicate of this submission is included for this purpose.

Respectfully submitted,

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Claims Appendix

1-49. (Cancelled)

50. A system for measuring physiological parameters in the body of a patient indicative of gastroesophageal reflux, the system comprising:

a monitoring device, said monitoring device comprising a housing adapted to be implanted in the body of a patient by attachment to tissue inside the body and a plurality of sensors included in said housing, wherein each of the plurality of sensors is capable of independently measuring a different respective physiological parameter indicative of gastroesophageal reflux and wherein said monitoring device periodically transmits a signal indicative of the value of the respective physiological parameter measured by each of the plurality of sensors; and

a receiver that receives the signals from the monitoring device, said signals representing measurements made by the respective plurality of sensors, monitors the physiological parameters indicative of gastroesophageal reflux based on the received signals, and determines at least the presence of gastroesophageal reflux based on each of said plurality of signals received from said plurality of sensors.

51. The system of Claim 50, wherein at least one of said plurality of sensors includes a pH monitor.

52. The system of Claim 51, wherein said monitoring device further includes a radio frequency (RF) transmitter and a microprocessor that periodically receives a signal

from the pH monitor and induces the RF transmitter to periodically send an RF signal indicative of the pH measured by the pH monitor.

53. The system of Claim 52, wherein the microprocessor periodically enables the pH monitor of the monitoring device during a first interval of each measurement cycle to obtain the pH signal and then disables the pH monitor during a second interval.

54. The system of Claim 53, wherein the microprocessor enables the RF transmitter during the second interval and disables the RF transmitter during periods of each cycle other than the second interval and disables the pH monitor during periods of each cycle other than the first interval.

55. The system of Claim 50, wherein each of the signals includes an identifier that is indicative of the monitoring device from which the signal is sent and wherein the identifier for each of the signals comprises at least one of a frequency or a code.

56. The system of Claim 50, wherein the receiver is configured to be worn by the patient.

57. The system of Claim 50, wherein the receiver includes circuitry to sense a position of the patient, and the receiver periodically records the position of the patient.

58. The system of Claim 50, wherein the receiver monitors a change in pH as a function of distance from a lower esophageal sphincter.

59. The system of Claim 50, wherein said plurality of sensors include a pH monitor and an auxiliary sensor, wherein said auxiliary sensor is to measure an auxiliary physiological parameter that is not a pH parameter, wherein the receiver is configured to receive a pH reading from said pH sensor and to adjust said pH reading based on the measured value of the physiological parameter.

60. The system of Claim 59, wherein the auxiliary physiological parameter is selected from the group consisting of: an ion concentration, a temperature, and a pressure.

Evidence Appendix

No evidence is submitted with this Appeal Brief.

Related Proceedings Appendix

There are no related proceedings known to the Appellants related to this application.